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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,450	12/02/2004	Gary E Gilbert	US 1418/04 (BWH)	2998

7590 01/26/2007

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EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,450	GILBERT ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20041202; 20061204*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-6 in the reply filed on November 21, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 7-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 21, 2006.

Priority

3. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is June 7, 2002.

Information Disclosure Statement

4. The information disclosure statements (IDSs) submitted on December 2, 2004, and December 4, 2006 are being considered by the examiner.

Drawings

5. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 1-4, 6, and 7 lack a description on the y-axis. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informalities:

7. On page 18, line 21, the word, "and" or a "," is missing after the concentration of factor X (100 nM). Suggest, "...factor X (100 nM), factor VIIa (100 pM) and varied concentrations of ...".

Appropriate correction is required.

Claim Objections

8. Claim 5 is objected to because of the following informalities:

9. There is a typographical error. The second to last "factor Ixa" is identified as "faxtor Ixa".

Appropriate correction is required.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-12, and 22-25 of copending Application No. 10/562,269. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a method of blocking or reducing the binding of a protein to a binding site, wherein the binding site is subjected to a binding agent selected from a group consisting of lactadherin, a fragment of lactadherin, a functional equivalent of lactadherin, and a functional equivalent of a fragment of lactadherin. The binding site comprises a phospholipids or lipoprotein, or phosphatidylserine. The protein encompasses the coagulation proteins. The copending claims are also directed to a method of blocking or reducing procoagulant activity of a cell by subjecting the cell to an agent selected from the previously recited Markush group. The instant claim 2 describes the procoagulant molecule as part of a cell membrane. The methods encompass the same step of subjecting lactadherin, with the same end result of reducing binding between a procoagulant molecule and a coagulation molecule.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112, Second Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method of performing the end effect of blocking or reducing access to a procoagulant molecule by a coagulation molecule is missing. How does subjecting a procoagulant molecule to lactadherin result in the method as claimed?

15. Claims 2-6 fail to cure the indefiniteness of claim 1.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected because the description of a procoagulant molecule is not adequately described. The claims are rejected under 35 U.S.C. 112, first paragraph, written

description as well because the fragment of lactadherin, a functional equivalent of lactadherin, or functional equivalent of a fragment of lactadherin is not adequately described. The genus of coagulation molecules in claims 1-4, and 6 are not adequately described. Furthermore, in claim 2, the cell membrane or a fragment thereof also lacks adequate description.

The instant claims are directed to a method of blocking or reducing access to a procoagulant molecule by a coagulation molecule comprising subjecting a procoagulant molecule to lactadherin, a fragment of lactadherin, a functional equivalent of lactadherin, or a functional equivalent of a fragment of lactadherin. The procoagulant molecule comprises a phospholipid or a lipoprotein, or phosphatidylserine.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and

knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claims 1-6 are directed to the method of blocking or reducing access to a procoagulant molecule by a coagulation molecule, comprising subjecting a procoagulant molecule to lactadherin, a fragment of lactadherin, a functional equivalent of lactadherin, or a functional equivalent of a fragment of lactadherin.

Second, how does the scope of the claims compare to the scope of the disclosure? The scope of the claims is broader in scope than the scope of the disclosure. The claims encompass any undefined procoagulant molecule. The dependent claims attempt to limit the procoagulant molecule to comprise a phospholipids, a lipoprotein, or a phosphatidylserine, but the disclosure does not describe the structure of a phospholipid, a lipoprotein, or the phosphatidylserine. In addition, there is no structural description of the fragments of lactadherin, or any functional equivalents of lactadherin or functional equivalents of lactadherin fragments. There is adequate description of the coagulation molecule recited in the Markush group of claim 5, but not to the genus of coagulation molecules recited in claims 1-4, and 6.

Third, the factors need to be considered.

(1) What was actually reduced to practice?

The method using full-length lactadherin to inhibit the binding of factor V, factor VII, factor IX, and factor X to a phospholipid composition comprising at least 4% phosphatidylserine was actually reduced to practice.

(2) Is there disclosure of drawings or structural chemical formulas?

No general structure is provided for each species of procoagulant molecules. No general structure is provided for each species of lactadherin fragments or any functional equivalents thereof. There is no disclosure of how any particular structure gives rise to the function of interaction between any procoagulant molecule with any fragment of lactadherin.

(3) Are there sufficient relevant identifying characteristics disclosed?

The functional characteristics of the inhibition of activation for coagulation factors based on the occupation of lipid binding sites by lactadherin are disclosed, but they are not coupled with a known or disclosed correlation between function and structure. The structural features of any fragments of lactadherin that could bind to any structural lipid binding sites are not disclosed.

(4) Is there at least one method of making the claimed invention disclosed?

There are assays that describe the inhibition of coagulation factors binding to phosphatidylserine containing phospholipids due to the presence of full-length lactadherin.

(5) What is the level of skill in the art and what knowledge is present in the art?

The level of skill in the art of phospholipid chemistry is high, about that of a PhD scientist with several years' experience.

The art has described the requirement of distinct structural phospholipid molecules for interaction between coagulation molecules and activating substrates. Gilbert and Arena (IDS document) describe the requirement of unsaturated phospholipid acyl chains and sn-2 acyl chain of phosphatidyl-L-serine for factor VIII binding sites. The lyso-PS did not support binding of factor VIII even when phosphatidylethanolamine and phosphatidylcholine contained unsaturated acyl chains (see Abstract and page 13532, last paragraph of Results and Figure 6).

(6) What is the level of predictability of the art?

The level of predictability in this art is very low, since there is no information upon which to base a prediction of what might be suitable as lipid interacting molecules with any procoagulant molecules comprising any phospholipid or lipoprotein for any lactadherin fragments.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the genus of the claimed invention.

Conclusion

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 16, 2007

ROBERT A. WAX
PRIMARY EXAMINER